X. 510(k) Summary

K062814

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
	DEC 15 2006
CONTACT PERSON:	Daphney Germain
DATE PREPARED:	September 18, 2006
CLASSIFICATION NAME:	Retractor, Self-Retaining, For Neurosurgery §882.4800
PROPRIETARY NAME:	PIPELINE II Access System
PREDICATE DEVICE:	Bright Medical Dilation Retractor System, K992898
DEVICE DESCRIPTION:	The PIPELINE II Access System consists of a series of dilators and tubular retractors with integrated light source of various lengths and diameters to provide access to the spine for minimally invasive procedures. The PIPELINE II Access System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.
INTENDED USE:	The PIPELINE Access System is intended to provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the port, down to the lamina, with its attachment to a rigid arm to provide a self-locking method of access to the spinal site which can be visualized using a microscope or loupes, and through which surgical instruments can be manipulated.
MATERIALS:	Manufactured from ASTM 17-4 PH Stainless Steel, Barium-filled Radel or Polyetheretherketone (PEEK), epoxy, and glass fiber optics.
PERFORMANCE DATA:	Performance data were submitted to characterize the PIPELINE II Access System components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Spine
% Ms. Sharon Starowicz
Director, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767-0350

DEC 15 2006

Re: K062814
Trade/Device Name: PIPELINE II Access System
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-retaining retractor for neurosurgery
Regulatory Class: II
Product Code: GZT
Dated: November 15, 2006
Received: November 16, 2006

Dear Ms. Starowicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

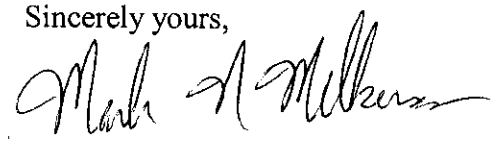
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use

510(k) Number (if known): K062814

Device Name: PIPELINE II Access System

Indications For Use:

The PIPELINE Access System is intended to provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the port, down to the lamina, with its attachment to a rigid arm to provide a self-locking method of access to the spinal site which can be visualized using a microscope or loupes, and through which surgical instruments can be manipulated.

Prescription Use: _____X_____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062814